

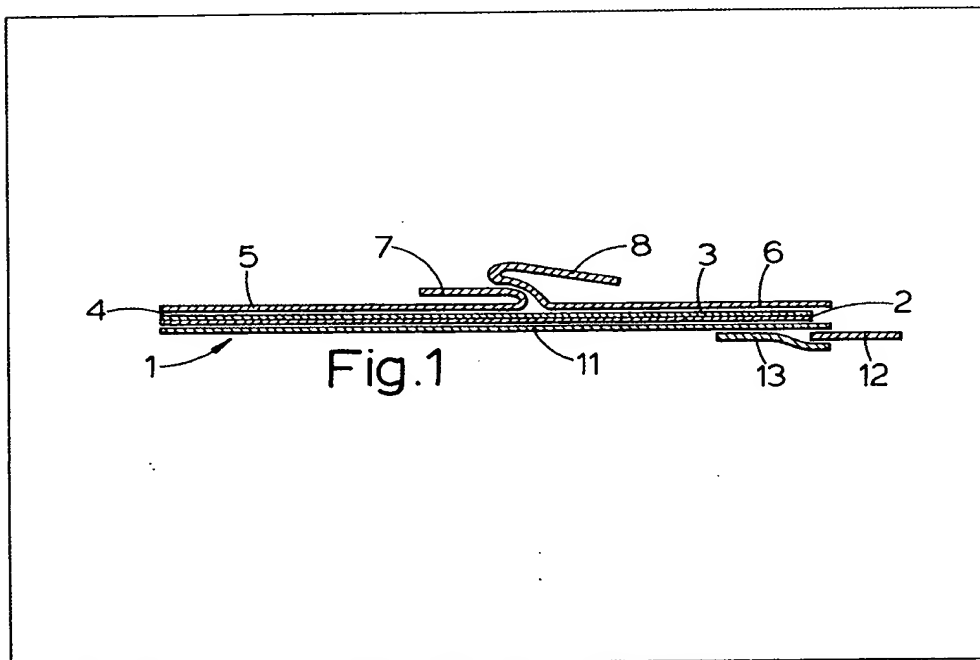
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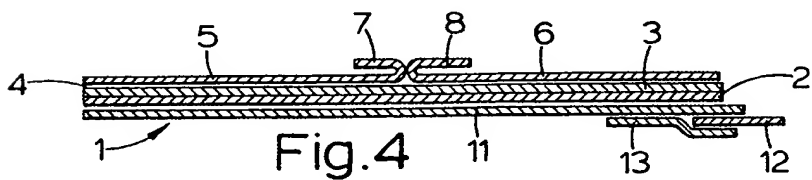
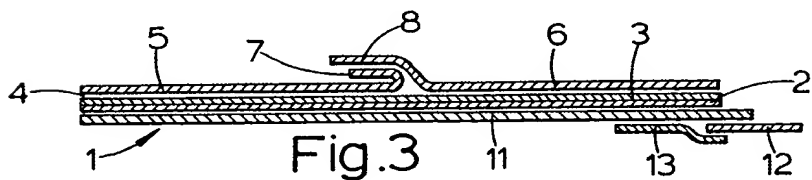
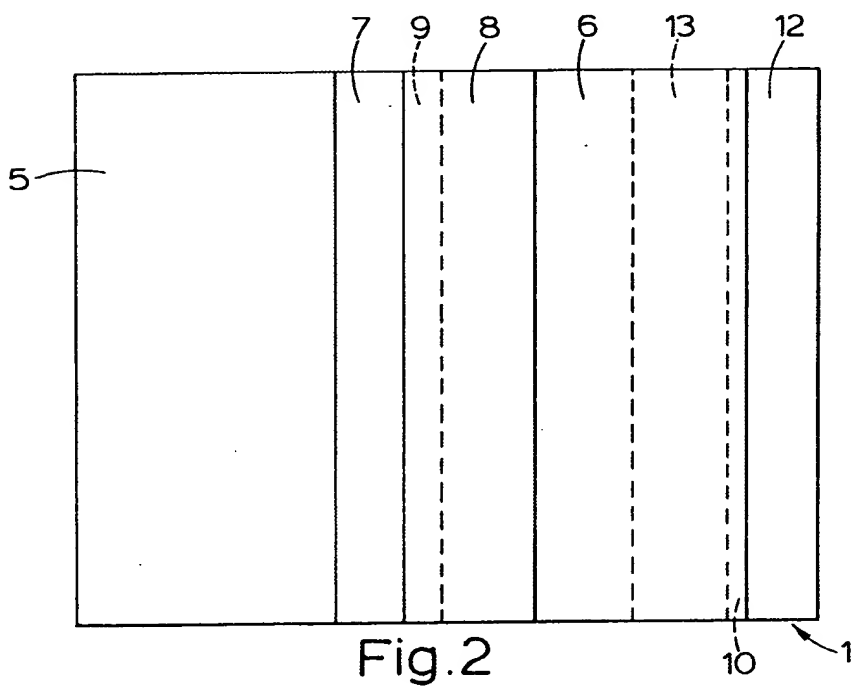
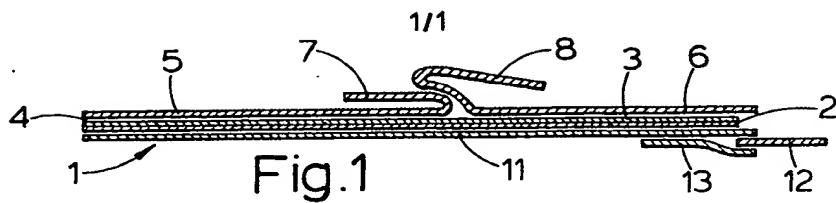
(54) Adhesive film dressing

(57) Adhesive dressing 1 comprises
a) a removable transparent
polymeric support layer 11, preferably
attached by means of adhesive tape 13
to a non-adhesive tab 12,
b) a bacteria-proof transparent film
2
c) an adhesive coating 3
d) a pair of release sheets 5, 6
having their free edges 7, 8 situated
away from the sides of the dressing, so
that the middle part of the dressing can
be applied first.



The drawings originally filed were informal and the print here reproduced is taken from a later filed formal copy.

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SPECIFICATION

Dressings

5 The present invention relates to adhesive dressings for use on skin and to the application of such dressings to the human body. In particular, this invention relates to self-adhesive conformable dressings in a presentation which allows easy and steril

10 application of the dressing.

Certain favoured self-adhesive conformable dressings known in the art usually comprise a polymeric film having an adhesive on at least part of its surface. Such dressings are sold for various uses which include attaching catheters to the body. Several presentations of such dressings are known and include the following:

A first dressing is known as Bioclusive Transparent Dressing (trade mark of Johnson and Johnson Products Inc.), which is a self-adhesive conformable film presented so that it is adhesive over the major part of one of its surface, leaving a non-adhesive tab at one side-edge, the total area of the film being co-terminous with a backing sheet to which the self-adhesive part of the film is adhered, the non-adhesive tab and the corresponding part of the backing sheet being perforated to allow removal of the tab.

A second dressing is known as Ensure (trade mark of Parke Davis and Co), which is a self-adhesive conformable film, presented with the adhesive surface of the film adhered to a removable backing sheet, the film having attached thereto, along one side-edge, a first non-adhesive tab, the non-adhesive surface of the film being covered with a removable protective layer which has, along one side-edge, a second non-adhesive tab attached by the side-edge of the tab remote from the centre of the protective layer.

A third dressing is known which is a self-adhesive conformable film, presented as described in European Patent Application No. 51,935. In one of these presentations, available as Tegaderm (trade mark of and available from Minnesota Mining and Manufacturing Co.) the adhesive surface of the film is adhered to a backing sheet or release liner, the backing sheet being wider than the film, thus forming a tab at one side-edge to allow removal of the backing sheet, the non-adhesive surface of the film being covered with a removable protective layer or releasable layer having a centre cut-out which, when removed, forms a window, the remaining frame being removable by means of a tab along its side-edge or by means of a split in the frame.

In each of the preceding known presentations, therefore, the means for releasing the backing sheet from the film is situated at a side-edge of the film. It has been found that this can result in difficulties in centring the dressing about a catheter (or part of the body), since one side of the dressing adheres to the catheter before the other side can be positioned. This in itself also leads to the possibility of 'rucking' of the dressing, leaving gaps around the catheter and surrounding skin which defeats the aim of sterility.

In a fourth known presentation which is described in European Patent Application No. 81990, published after the priority date of the application for the present invention a dressing, is known in which a backing layer is secured to the non-adhesive side of the film to improve handleability of the dressing. The backing layer is an opaque, fibrous material. This means that it is not possible to see through the dressing to accurately position it on the skin, particularly important when the dressing is to be used to surround a catheter. The dressings of the present invention overcome this disadvantage by providing a backing layer or support layer on the non-adhesive side of the film in the form of a transparent polymeric layer.

Other difficulties arising with the above-described hitherto-known presentations include major problems in applying the dressing without touching the adhesive, thereby defeating the aim of sterility.

The first dressing described above also suffers from the disadvantage of having to remove a tab from the dressing once it is in place; this can cause movement and rucking of the dressing.

The present invention helps overcome these problems by providing a dressing comprising a self-adhesive conformable film adhered to a removable protector, which protector has means in the form of handles for releasing it from the film, characterised in that the release means is situated away from the side-edges of the protector.

It is clear from the above therefore that the present invention provides an adhesive dressing suitable for use on the skin which comprises (a) a bacteria proof, transparent film coated with adhesive on one face, (b) a protector over the whole of the adhesive which protector consists of a first part and a second part, the first part disposed over one side of the dressing and the second part disposed over the remainder of the dressing said first and second parts being adapted to provide handles whereby said first and second parts can be grasped and peeled away from the adhesive and (c) a removable transparent polymeric film support layer over the non-adhesive face of the film.

The first and second parts of the protector together cover the whole of the adhesive face of the film. The two parts meet or overlap at a point away from the edge of the dressing. The two parts may be of unequal area but preferably will have an approximately equal area in contact with the adhesive face in which case they will meet or overlap about a line approximately at the centre of the dressing. Such a dressing in which the areas are equal is within the scope of the present invention.

Thus in a favoured aspect the present invention provides a dressing which comprises (a) a bacteria-proof transparent film adhesive film coated with adhesive on one face and (b) a protector over the whole of the adhesive which protector comprises a first and second part, the first part disposed to one side of the dressing and the second part disposed over the remainder of the dressing, said first and second parts abutting and each of said first and second parts possessing a portion bent back away from the plane of the dressing whereby said first and

second parts can be grasped and peeled away from the adhesive and (c) a removable transparent polymeric film support layer over the non-adhesive surface of the film.

- 5 Most aptly the first and second parts abut along an approximately central line across the face of the dressing.

This invention therefore includes the advantage of being able to position the dressing over a catheter (or part of the body) so that a middle part of the dressing first adheres to the catheter. By 'a middle part' is meant a part of the dressing which is not a side-edge. The protector can then be gradually released from the middle in a direction towards each side-edge, thereby greatly reducing the possibility of rucking the dressing and increasing the chances of maintaining sterility.

The two parts of the protector may abut each other where they meet or more preferably the second part may overlie a portion of the first part of protector without having a bent back portion or may overlie a portion of the first part of the protector and then have a bent back portion.

Thus in a preferred aspect the present invention provides an adhesive dressing suitable for use on the skin which comprises (a) a bacteria proof, transparent film coated with adhesive on one face, (b) a protector layer over the whole of the adhesive which protector comprises a first part and a second part, the first part disposed to one side of the dressing and the second part disposed over the remainder of the dressing, said first part possessing a portion which is bent back away from the plane of the dressing, said second part overlapping onto the first part over the bent back portion whereby said first and second parts can be grasped and peeled away from the adhesive and (c) a removable transparent polymeric film support layer over the non-adhesive face of the film.

In a further preferred aspect the present invention provides an adhesive dressing suitable for use on the skin which comprises (a) a bacteria proof, transparent film coated with adhesive on one face, (b) a protector layer over the whole of the adhesive which protector comprises a first part and a second part, the first part disposed to one side of the dressing and the second part disposed over the remainder of the dressing, each of said first and second parts possessing a portion bent back away from the plane of the dressing, the second part being adapted to overlap the first part at least over a part of the bent over portion of the first part whereby said first and second parts can be grasped and peeled away from the adhesive and (c) a removable transparent polymeric film support layer.

Preferably, in the dressing of this invention the removable support layer covering the non-adhesive surface of the film is such that the support layer is attached less tenaciously to the film than is the protector to the adhesive.

More preferably, the area of the removable support layer is co-terminous with the area of the film and has attached thereto, at one side-edge, and extending from the support layer, a tab to allow its removal. This overcomes the disadvantage of rigid-

ity exhibited by the frame of the third known presentation described above, allowing the dressing to be more easily applied to curved surfaces. This also overcomes the disadvantage of the tab arrangement of the second known presentation described above, where, in use, the angle at which the tab has to be pulled is such as to increase the likelihood of rucking of the dressing once in position.

The conformable bacteria proof film for use in the present invention is a transparent polymeric film so as to allow observation of the surface to which the dressing is to be adhered.

Examples of suitable films, and adhesives therefore, are described in British Patent Specification No. 1,280,631, European Patent Specification No. 51-935 (especially the polyurethanes) and films prepared from the hydrophilic polyurethanes disclosed in European patent Specification No. 50035 which patents are incorporated herein by cross-reference.

Films, and adhesives, described in these specifications as 'preferred' are also to be taken to be preferred for use in the dressing of this invention.

The adhesive coated film most suitably transmits moisture vapour at a rate of at least $300\text{g}/\text{m}^2/24\text{ hrs}/37^\circ\text{C}/100\text{-}10\%\text{ RH}$, more favourably at least $400\text{g}/\text{m}^2$, desirably at least $500\text{g}/\text{m}^2$ and preferably at least $700\text{g}/\text{m}^2$ (when measured by the Payne Cup Method).

The film is desirably formed a synthetic polymer including polyurethane and is 9 to 35 microns thick, more suitably 10 to 30 microns thick and preferably from 20 to 25 microns thick.

The adhesive may be an all over spread, pattern spread, a microporous layer or a porous layer or the like. The adhesive may be pattern spread using the method described in British patent No. 819,635. The adhesive may be formed as a porous layer by the method described in British Patent No. 1,563,695. Both these patents are incorporated herein by cross reference. However, it is preferred that the adhesive is in the form of an all over spread, that is as a continuous layer containing no pores or micropores.

Suitable adhesives which are moisture vapour transmitting as an all over spread or continuous layer include various acrylate ester copolymer and polyvinyl ether pressure sensitive adhesives for example as disclosed in British Patent No. 1,280,631. Favoured pressure sensitive adhesives comprise copolymers of acrylic ester with acrylic acid for example as disclosed in United Kingdom Application No. 2,070,631.

A preferred pressure sensitive adhesive comprises a blend of high and low viscosity polyvinyl ethyl ether disclosed in British Patent No. 1,280,631. A second preferred pressure sensitive adhesive is disclosed in United Kingdom Application No. 2,070,631 as a copolymer of 47 parts by weight 2-ethyl-hexylacrylate, 47 parts by weight butyl acrylate and 6 parts by weight of acrylic acid polymerised in acetone.

The adhesive is suitably employed at weights per unit area of $10\text{ to }75\text{g}/\text{m}^2$, more usually $15\text{ to }65\text{g}/\text{m}^2$, preferably at $25\text{ to }40\text{g}/\text{m}^2$ for example $29\text{g}/\text{m}^2$, $32\text{g}/\text{m}^2$.

The protector may be any convenient material

used for such purposes such as a polymer or paper film and especially those treated for easy release properties, for example by siliconisation.

The protector sheet for use in this invention may
5 comprise any material known to those skilled in the art or described in the above-listed specifications. Preferably, the protector is of transparent or translucent material which includes poly(vinyl chloride) or
10 or other siliconised polymers such as high or low density polyethylene which have been surface treated.

The support layer is most suitably formed from a transparent polymer such as polyethylene, polypropylene, polyamide, polyester or the like. Most
15 aptly the support layer is adapted for easy release from the film, for example by including a blocking compound or silicone coating. Generally the layer is 12 to 35 microns thick, more aptly 15 to 30 microns,
20 for example 20 to 25 microns thick.

The removable support layer present in this invention may be made of any suitable transparent polymeric film material which allows the dressing to
25 be positioned over curved surfaces. Such materials include low or high density polyethylene, polypropylene, polystyrene, cellophane, nylon, polyester or the like.

In another aspect, the present invention therefore provides a method of applying a dressing as
30 hereinbefore described which method comprises positioning the dressing over the surface to which it is to be applied, such that the protector is adjacent the surface, and removing the protector from the film, characterised in that the first part of the
35 dressing to adhere to the surface is away from the side-edges of the protector and then removing a support layer from the non-adhesive surface of the film.

Especially preferred is a method wherein release
40 means, situated away from the side-edges of the protector, are used to release the protector.

In a further aspect, the present invention provides a method of preparing such a dressing as hereinbefore described comprising applying adhesive to at
45 least a part of a conformable transparent polymeric film, affixing to said part of the film a protector layer having means for removing the protector from the film which means is situated away from the side-edges of the film, and sterilising the resulting
50 dressing. The method further includes the step of less tenaciously affixing a removable, support layer to the non-adhesive surface of the film.

More preferably, the method still further includes the step of attaching a non-adhesive tab to the
55 support layer.

The dressings of this invention may be made by (a) extruding the polymer which is to form the film layer through a die of the appropriate size on to the material which is to form the support layer which is typically in film form. An adhesive layer may be cast
60 from solution onto a siliconised release paper and then transfer coated onto the film face of the laminate formed above to form an adhesive strip. The protector is then applied to adhesive face of the
65 strip and the resulting strip cut to form dressings of

the desired size; (b) the polymer which is to form the film and the material which is to form the support layer may be coextruded to form a laminate strip of the required thicknesses. The adhesive and protector
70 are then transferred to the strip in a conventional manner; (c) the polymer which is to form the film may be cast onto the support layer from a solution or syrup, the solvent of which will not effect the support layer. After removal of the solvent, a preformed
75 adhesive layer may be transfer coated onto the film face and finally the protector added.

A further step which may be included in the preparation is to attach a non-adhesive tab to the one edge of the support layer by means of a thin
80 strip of adhesive tape.

Once the dressings have been cut to size they may be individually placed in bacteria proof packages and the package sealed and sterilized in the normal way.

85 In a still further aspect, the present invention provides a sterile dressing according to the invention contained in a bacteria-proof package.

Such packages include those made from paper, plastic or aluminium foil.

90 Preferably, the package contains or incorporates instructions on how to use the dressing according to the invention.

One favoured form of this invention comprises a dressing 10cm x 10cm which is a 25 micron thick
95 polyurethane film (such as an Estane 5701F, trade mark of B.F. Goodrich) coated over one face with a 25 micron thick layer of acrylic adhesive (such as the preferred adhesive of European patent Application No. 51935) in which dressing a 20 micron thick film
100 of low density polyethylene which has been siliconised acts as support layer and a protector comprises two 10cm x 6cm pieces of siliconised glassite paper placed so that each has a 10cm x 5cm portion which overlays the adhesive and a 10cm x 1cm strip
105 folded back to provide a handle.

Such devices overcome the disadvantages of the devices of European Patent Application No. 51935 such as the inflexibility introduced by using a "frame".

110 The present invention will now be illustrated by way of example only, with reference to the accompanying drawings in which:

Figure 1 shows a cross-sectional view of a dressing according to this invention; and

115 *Figure 2* shows a plan view of a dressing according to this invention.

Figure 3 shows a cross-section view of a dressing according to another aspect of this invention;

Figure 4 shows a cross-section view of a dressing according to another aspect of this invention.

Referring first to *Figure 1*, the dressing 1 comprises a conformable film 2 of polyurethane on one surface of which is spread an acrylic adhesive 3 to which surface is adhered a protector 4 of poly(vinyl chloride) or siliconised paper.

125 The protector 4 just overlaps the film 2 and is in two parts 5 and 6. Each of the two parts 5 and 6 terminate towards the middle (but not necessarily in the centre) of the sheet 4 in tabs 7 and 8 which
130 overlap so that the total surface of the adhesive 3 is

covered.

Figure 2 shows the extent of the overlapping 9 between tabs 7 and 8; and also the overlapping 10 between protector 4 and film 2.

- 5 Referring back to Figure 1, in this embodiment of this invention, there is a support layer 11 over the non-adhesive surface of film 2 made of polyethylene. A tab 12 is provided at one edge of the layer 11, extending therefrom and attached thereto by tape 13. Both tab 12 and tape 13 are transparent, 10 tab 12 being a blue colour to allow easy identification during use.

- In use, the device 1 is positioned so that overlap 9 (Figure 2) is over that part of the catheter (or other surface) which centralised the dressing about the catheter. Tabs 7 and 8 are grasped and gradually pulled toward the corresponding edges of the dressing exposing adhesive 3, and gentle pressure is applied so that the dressing adheres to the catheter. 15 The two parts 5 and 6 of the protector 4 are thus removed entirely and disposed of. Next, blue tab 12 on support layer 11 is grasped and pulled towards the middle of the device so that support layer 11 is gradually removed and then disposed of. Thus, film 20 2 remains adhered to the catheter by adhesive 3.

Figure 3 shows a similar dressing to that described in Figure 1 except that the second part of the protector 6 instead of having a bent back portion 8, overlaps onto the first portion of the protector 5.

- 30 Figure 4 shows a similar dressing to that described in Figure 1 except that the first and second parts of the protector abut each other and do not overlap.

- The adhesive films employed in this invention may be represented by a membrane coated over one surface with an adhesive layer. Most suitably the membrane is 10 to 40 microns thick and preferably 35 from 20 to 35 microns thick, for example 25 microns thick. Most suitable the adhesive layer is 15 to 65 microns thick and preferably from 20 to 40 microns 40 thick, for example 25 to 35 microns thick. Desirably both membrane and adhesive are formed from moisture vapour permeable materials.

- Preferably the protector is in two parts which are approximately equal in size so that the two parts 45 come together at approximately the middle of the sheet. Preferably each of the two parts of the protector is adapted to provide handles for example in the form of tabs projecting away from the middle of the sheet (that is part of each of the two parts of the backing sheet is folded back upon itself providing 50 handles).

This invention is particularly effective for materials having an extension of at least 300% at 300kg/sq. cm.

55 EXAMPLE 1.

Preparation of an adhesive dressing

- A syrup of a polyurethane (Estane 5701F, trade mark of B.F. Goodrich) in tetrahydrofuran/acetone, (solids content 15%) is cast onto a film of a polyester 60 (Melinex, trade mark of I.C.I.) to form a film of polyurethane which is 25 microns in thickness.

- A solution of an acrylic ester copolymer, formed from the copolymerisation of 47 parts 2-ethylhexylacrylate, 47 parts butylacrylate and 6 parts of 65 acrylic acid is spread onto silicone release paper and

the solvent removed to give an adhesive layer at a weight of 29 gm².

The adhesive layer is then transfer coated onto the polyurethane face of the laminate formed above.

- 70 The two part protector layer is then transferred to the adhesive coated laminate so as to cover the whole of the adhesive surface.

- A non-adhesive tab is then adhered to the one edge of the polyester film by means of an adhesive 75 tape.

The dressing strip so formed is then cut to the appropriate size.

- The individual dressings may be placed and sealed in a bacteria proof pack and the package 80 sterilised by conventional means.

- In use, the sterile dressing is removed from the pack, the two parts of the protector peeled a little back so as to expose a small area of adhesive which is then accurately placed on the body. The remaining 85 adhesive surface is exposed by peeling back the protector and the dressing smoothly applied to the skin. The tab is then used to remove the support layer from the non-adhesive face of the dressing.

90 EXAMPLE 2.

Preparation of an adhesive dressing

- A polyurethane (Estane 58201, trade mark of B.F. Goodrich) is extruded onto a 20 micron thick film of low density polyethylene the surface of which has 95 been siliconised, to form a film of polyurethane 25 microns thick.

- An adhesive layer is formed on a siliconised release paper as described in Example 1. The adhesive layer is transfer coated onto the 100 polyurethane face of the polyurethane-polyethylene laminate.

- The two part protector is then placed on the adhesive surface and finally a non-adhesive tab is adhered to one edge of the polyethylene support 105 layer using a thin strip of adhesive tape.

The dressing may be packaged and used as described in Example 1.

CLAIMS

- 110 1. An adhesive dressing suitable for use on the skin comprises (a) a bacteria proof, transparent film coated with adhesive on one face, (b) a protector over the whole of the adhesive which protector 115 consists of a first part and a second part, the first part disposed over one side of the dressing and the second part disposed over the remainder of the dressing said first and second parts being adapted to provide handles whereby said first and second parts 120 can be grasped and peeled away from the adhesive layer over the non-adhesive face of the film.
2. An adhesive dressing suitable for use on the skin comprises (a) a bacteria proof, transparent film coated with adhesive on one face, (b) a protector 125 layer over the whole of the adhesive which protector comprises a first and second part, the first part disposed to one side of the dressing and the second part disposed over the remainder of the dressing, 130 said first and second parts abutting and each of said

first and second parts possessing a portion bent back away from the plane of the dressing whereby said first and second parts can be grasped and peeled away from the adhesive and (c) a removable, transparent polymeric layer over the non-adhesive face of the film.

3. An adhesive dressing suitable for use on the skin comprises (a) a bacteria proof, transparent film coated with adhesive on one face, (b) a protector layer over the whole of the adhesive which protector comprises a first and second part, the first part disposed to one side of the dressing and the second part disposed over the remainder of the dressing, said disposed over the remainder of the dressing, said first part possessing a portion which is bent back away from the plane of the dressing, said second part overlapping onto the first part over the bent back portion whereby said first and second parts can be grasped and peeled away from the adhesive and (c) a removable transparent polymeric support layer over the non-adhesive face of the film.

4. An adhesive dressing suitable for use on the skin comprises (a) a bacteria proof, transparent film coated with adhesive on one face, (b) a protector layer over the whole of the adhesive which protector comprises a first and second part, the first part disposed to one side of the dressing and the second disposed over the remainder of the dressing, each of said first and second parts possessing a portion bent back away from the plane of the dressing, the second part being adapted to overlap the first part at least over a part of the bent over portion of the first part whereby said first and second parts can be grasped and peeled away from the adhesive and (c) a removable transparent polymeric support layer over the non-adhesive face of the film.

5. An adhesive dressing as claimed in any of claims 1 to 4 in which the first part and second part of the protector are approximately equal in size so that they come together approximately at the middle of the adhesive coated face of the dressing.

6. An adhesive dressing as claimed in any of claims 1 to 5 in which the support layer is a siliconised low density polyethylene film.

7. An adhesive dressing as claimed in any of claims 1 to 5 in which the support layer is a polyester film.

8. An adhesive dressing as claimed in any of claims 1 to 7 in which the thickness of the support layer is from 12 to 35 microns.

9. An adhesive dressing as claimed in any of claims 1 to 8 in which the adhesive coated film has a moisture vapour transmission rate of at least 300g/m²/24 hrs. when measured at 37°C and 100% to 10% relative humidity.

10. An adhesive dressing as claimed in any of claims 1 to 9 in which the film is formed from a polyurethane which is from 9 to 35 microns in thickness.

11. An adhesive dressing as claimed in any of claims 1 to 10 in which the adhesive is a polyvinyl ethyl ether adhesive.

12. An adhesive dressing as claimed in any of claims 1 to 10 in which the adhesive is an acrylate ester adhesive.

13. An adhesive dressing as claimed in any of claims 1 to 12 in which the weight per unit area of the adhesive is from 10 to 75g/m².

14. An adhesive dressing as claimed in any of claims 1 to 13 in which the protector is a siliconised glassite paper.

15. An adhesive dressing as claimed in any of claims 1 to 14 in a sterile form and packaged in a bacteria proof pack.

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